

DEC 12 2003

K033735

510(k) SUMMARY SAFETY AND EFFECTIVENESS

- A. Submitted By: ADAC Laboratories
540 Alder Dr.
Milpitas, CA 95035
Contact: Charlene Brumbaugh
Tel: (408) 468-3619
Fax: (408) 468-3050
- B. Device Trade Name: Vantage™ Pro
Common Name: Attenuation Correction Device
Classification Name: System, Emission Computed Tomography
Device Class: 21 CFR 892.1200, Class II
Product Code: 90 KPS
- C. Date prepared: November 12, 2003
- D. Predicate Device: Vantage ExSPECT II (K992078)
- E. Intended Use:

The Vantage Pro Attenuation Correction Device option to gamma camera systems marketed by ADAC, a Philips Medical Systems Company, produces images that depict the anatomical density of a patient. The system is intended to provide an enhancement to the emission images acquired using the gamma camera system by correcting for attenuation effects in the patient. Vantage Pro includes additional quality assurance tools to evaluate the resulting density image.

F. Device Description:

Vantage™ Pro (with ExSPECT™ III a truncation compensation algorithm) is an attenuation correction device, which will be marketed as an optional addition to ADAC Laboratories Gamma Camera products or cameras marketed by ADAC.

Vantage Pro is an option that provides a patient's functional information, which is further improved by using the anatomical information, obtained using the external radioactive scanning line sources with special collimation to minimize patient exposure.

In operation, the Vantage system utilizes two 250 mCi, easily managed, shielded radioactive scanning line sources containing ¹⁵³GD, which are attached to an ADAC gamma camera or a gamma camera marketed by ADAC. They are positioned opposite each of the two detectors with parallel hole collimation while in 90-degree orientation. When a shutter on the shielded source is opened, a collimated beam of gamma ray photons is focused at each opposing detector to form a transmission image of a patient placed in the field of view. Simultaneously,

emission data is collected from the patient. Both sets of data are acquired and processed to produce an attenuation corrected emission image via MLEM iterative reconstruction that is better than a conventional Single Photon Emission Computed Tomography (SPECT) image.

The MLEM reconstruction with attenuation correction includes image quality enhancements by correcting for the photopeak scatter via single energy window subtraction, downscatter via single energy window subtraction, and resolution recovery (RR). Also provided is a Post Acquisition QA tool that provides the user with feedback regarding the quality of the acquired images in that it alerts the user as to the level of any banding or truncation in the data as well as the level of counts acquired in each data set.

The attenuation correction method includes a user-selectable Bayesian iterative reconstruction method, or an ordered subset expectation maximization (OSEM) method, for reconstructing the transmission map. The Bayesian method is an iterative method that reduces image noise. The key components in this method are using a gamma prior to constrain the results, and a gradient algorithm approach for determining updates. In addition, this method includes a prior for reducing noise in poor count regions and reducing biases in the soft tissue region in the transmission data set. Vantage Pro improves the Bayesian method by incorporating a new algorithm to compensate for truncation of the transmission map.

Vantage Pro (with ExSPECT III) is a modification of Vantage ExSPECT II. The algorithm modification updates the Bayesian attenuation correction algorithm to compensate for the truncated attenuation map (ExSPECT III) that may result from having a patient larger than the camera field of view.

The Post Acquisition QA tool consists of three components: banding detection, truncation detection, and count level determination. Banding refers to the presence of bright sections or strips in the acquired image data set caused by a highly irregular heartbeat. Truncation occurs when a portion of the patient's body is not fully captured within the dimensions of the acquired image. Reconstruction of an image data set which exhibits truncation or banding would yield inappropriate clinical data containing major artifacts. The Post Acquisition QA tool detects banding or truncation which allows the user to reassess the image. In addition, this tool informs the user whether the image contains sufficient count density that would ensure proper data reconstruction. These features are of informative nature only, so that the raw data is not altered. The user may then use the warning information, raw data, and their own clinical experience to proceed with a diagnostic decision.

G. Technological Comparison

The modified device, Vantage Pro, offers all of the features of the existing device, Vantage ExSPECT II (K992078), while modifying the transmission reconstruction algorithm to compensate for truncated transmission images. The basic underlying

algorithm of the transmission map reconstruction remains a Bayesian Iterative method. A modification has been introduced to the definition of and use of the initial estimate (prior) to allow activity outside of the field of view of some projections to be estimated based on the projections in which data is present. As with the existing Vantage, the reconstructed transmission map is then used to correct the patient's emission data for non-uniform photon attenuation.

The modified device and the existing device have the same indications for use, same source type and geometry, same system hardware and same operating principles.

Both the modified Vantage Pro with ExSPECT III and the predicate Vantage ExSPECT II software programs provide a patient's functional information, which is further improved by using anatomical information, obtained using external radioactive scanning line sources, with special collimation to minimize patient exposure.

Both the modified Vantage Pro with ExSPECT III and the predicate Vantage ExSPECT II use the same imaging technique of SPECT with attenuation correction and image quality enhancements by correcting for the Photopeak scatter, Downscatter, and Resolution Recovery (RR).

H. Conclusion

The modified device, Vantage Pro, is substantially equivalent to the predicate device, Vantage ExSPECT II, based upon identical indications for use, technological comparison and overall system performance.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2003

ADAC Laboratories
% Mr. Morten Christensen
Office Coordinator, 510(k) Review Program
Underwriters Laboratories, Inc.
1655 Scott Boulevard
SANTA CLARA CA 95050-4169

Re: K033735
Trade/Device Name: Vantage™ Pro (with ExSPECT™
III a truncation compensation algorithm)
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed
tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: November 26, 2003
Received: November 28, 2003

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

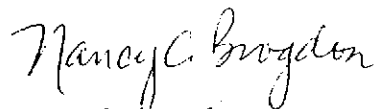
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510 (k) NUMBER (IF KNOWN): K033735

DEVICE NAME: Vantage™ Pro Attenuation Correction Device

SPONSOR NAME: ADAC Laboratories

INDICATIONS FOR USE:

The Vantage Pro Attenuation Correction Device option to gamma camera systems marketed by ADAC, a Philips Medical Systems Company, produces images that depict the anatomical density of a patient. The system is intended to provide an enhancement to the emission images acquired using the gamma camera system by correcting for attenuation effects in the patient. Vantage Pro includes additional quality assurance tools to evaluate the resulting density image.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2-96)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033735